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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/603,131	06/23/2000	Bethany A. Janowski	UTSD:578USC2/RAN	3524

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Richard A Nakashima  
Fulbright & Jaworski LLP  
600 Congress Avenue  
Suite 2400  
Austin, TX 78701

EXAMINER

PAK, MICHAEL D

ART UNIT

PAPER NUMBER

1646

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/603,131

Applicant(s)  
Janowski et al.

Examiner  
Michael Pak

Art Unit  
1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on May 29, 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 17-23 is/are pending in the application.
- 4a) Of the above, claim(s) 2 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-8, and 17-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Preliminary amendment filed 23 June 2000 (Paper No. 2) has been entered.
2. Applicant's election without traverse of Group I, claims 1, 3-8, and 17-23, in Paper No. 6 is acknowledged.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 3-8 and 17-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "LXR expression construct" which is not defined or limited in terms of structure and the metes and bounds are unclear. Claim 3 recite Markush groups of names directed to LXR constructs without structure and the metes and bounds are unclear. Claims 4-8 and 17-23 are dependent on claim 1.

Claim 1 recites the limitation "LXR $\alpha$  protein" which is not defined or limited in terms of structure and the metes and bounds are unclear. Claims 3-8 and 17-23 are dependent on claim 1.

Claim 1 recites the limitation "oxysterol activator" which is not defined or limited in terms of structure and the metes and bounds are unclear. Claims 3-8 and 17-23 are dependent on claim 1.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 3-8 and 17-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed method using LXR expression construct of examples 1-6 of the specification where the claim limitation clearly limits the structure of the construct, does not reasonably provide enablement for an LXR construct where no structural limitations are provided in the claim. The specification does not enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims encompass LXR defined by function which is not defined in the specification. Thus, claims encompass mutants and variants of LXR. However, the state of the art at the time of the invention was such that one skilled in the art did not know the ligand for the LXR receptor of the specific species disclosed by Willy et al.(C29). Furthermore, even after the time of the invention, Lala et al.(C21; page 5, first paragraph, last line) teach that AF-2 domains are required for the specific species for function. One skilled in the art cannot make and use the scope of LXR claimed because specific domains of the receptor are required for function such as the ligand binding domain, the DNA binding domain, the heterodimerization domain, and the activation domains, and each of these domains must act in concert with one another. It would require undue experimentation to make and use the full scope of the claimed invention.

7. Claims 3, 6 and 19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

A deposit of the constructs listed in Markush groups are required to enable the invention of claims 3, 6 and 19. The scope of the claim is interpreted to mean a deposited construct in order to expedite prosecution until the term is clarified. This determination has been made because the claimed constructs have not been fully disclosed or the materials required to construct the claimed cell has not been shown to be publicly known and fully available. The specification does not teach how to make the disclosed constructs, in a sufficient manner to practice the invention because one skilled in the art could not determine the exact materials necessary to make the constructs. It would require undue experimentation to determine the exact materials necessary to make the constructs. Without a publicly available deposit of the above vectors or strains, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. A suitable deposit for patent purposes is required.

If a deposit has been made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating (a) that the deposit has been made under the terms of the Budapest Treaty; and (b) that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 C.F.R. § 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then the requirements may be satisfied by an affidavit or declaration by Applicants or someone associated with the patent

owner who is in a position to make such assurances, or by a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and establishing that the following criteria have been met: (a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto; (b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent; (c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material; (d) a viability statement in accordance with the provisions of 37 C.F.R. § 1.807 is provided; and (e) the deposit will be replaced should it become necessary due to inviability, contamination, or loss of capability to function described in the manner in the specification.

In either case, the identifying information set forth in 37 C.F.R. § 1.809(d) should be added to the specification if it is not already present. See 37 C.F.R. §§ 1.803-1.809 for additional explanation of these requirements.

### ***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

9. Claims 1, 3-8 and 17-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Willy et al. ((C29); Genes and Dev., 1995).

Willy et al. disclose the method of ligand screening with LXR expressing host cell with a reporter construct (figures 4-7). The host cell is the CV-1 cell and luciferase activity is detected from the reporter (figure 4). Various candidate ligands are screened with the method (figure 4).

The terms "LXR expression construct", "LXR $\alpha$  protein", "oxysterol activator" are not defined or limited in terms of structure. Thus, Willy et al. methods encompass the claim limitations.

10. Claims 1, 3-8 and 17-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Hogness et al. ((A); US 5,514,578).

Hogness et al. disclose ecdysteroid receptor construct methods for screening ligand meeting the limitations of the claims (columns 6-20). Ecdysteroids are encompassed by the term oxysteroids because the specification does not define the term. Since ecdysteroids are oxysteroids, the Hogness et al. ecdysteroid receptor is encompassed by the generic LXR protein. The terms "LXR expression construct", "LXR $\alpha$  protein", "oxysterol activator" are not defined or limited in terms of structure. Thus, Hogness et al. methods encompass the claim limitations.

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11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-2731.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Michael D. Pak*  
Michael Pak  
Patent Examiner  
Art Unit 1646  
25 June 1998